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Vitamin A

DEFINITION

Vitamin A contains a suitable form of retinol ($C_{20}H_{30}O$; vitamin A alcohol) and possesses vitamin A activity equivalent to NLT 95.0% of that declared on the label. It may consist of retinol or esters of retinol formed from edible fatty acids, principally acetic and palmitic acids. It may be diluted with edible oils, or it may be incorporated in solid edible carriers or excipients, and it may contain suitable antimicrobial agents, dispersants, and antioxidants.

IDENTIFICATION

- **A. Color Reaction with Antimony III**

  Sample solution: Vitamin A equivalent to 6 µg/mL of retinol in chloroform

  Analysis: To 1 mL of the *Sample solution* add 10 mL of antimony trichloride TS.

  Acceptance criteria: A transient blue color appears at once.

- **B. Thin-Layer Chromatography**

  Standard solution: USP Retinyl Acetate RS and USP Retinyl Palmitate RS in methylene chloride, each equivalent to about 0.2 mg/mL of retinol ($C_{20}H_{30}O$)

  Sample solution for the liquid form of Vitamin A: Dissolve a volume, equivalent to about 5 mg of retinol, in methylene chloride to obtain 10.0 mL of solution.

  Sample solution for the solid form of Vitamin A: Transfer a quantity, equivalent to about 5 mg of retinol, to a separator, add 75 mL of water, and shake vigorously for 1 min. Extract with 10.0 mL of methylene chloride by shaking for 1 min, and centrifuge to clarify the methylene chloride extract.

  Chromatographic system

  (See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

  Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

  Application volume

  Standard solution: 15 µL

  Sample solution: 10 µL

  Developing solvent system: Cyclohexane and ether (4:1)

  Developing distance: 10 cm

  Spray reagent: Phosphomolybdic acid TS

  System suitability

  Sample: *Standard solution*

  Suitability requirements: The chromatogram shows two main blue-green spots of the corresponding esters. The R_F values are 0.45 ± 0.10 and 0.7 ± 0.1 for retinyl acetate and retinyl palmitate, respectively.

  Analysis

  Samples: *Standard solution* and the appropriate *Sample solution*

  Allow the solvent front to move a distance of 10 cm, remove the plate, and air-dry. Spray the plate with *Spray reagent*.

  Acceptance criteria: The appropriate *Sample solution* exhibits a main blue-green spot at an R_F value that corresponds to one of the two main spots from the *Standard solution* and is consistent with the labeled ester. The appropriate *Sample solution* of Vitamin A labeled as containing retinol exhibits the main blue-green spot at an approximate R_F value of 0.1.

ASSAY

- **Vitamin A Assay ⟨571⟩**

  Sample: Use a suitable quantity of Vitamin A.

Analysis: Proceed as directed in *Vitamin A Assay ⟨571⟩, Assay, Chemical Methods* or *Chromatographic Methods*, depending on the form of Vitamin A under test.

Acceptance criteria: Equivalent to NLT 95.0% of the labeled amount of vitamin A activity

SPECIFIC TESTS

• **Absorbance Ratio**

[Note—This test is required only if *Vitamin A Assay ⟨571⟩, Assay, Chemical Methods* is used for the *Assay*.]

Sample: Use a suitable quantity of Vitamin A.

Analysis: Proceed as directed in *Vitamin A Assay ⟨571⟩, Assay, Chemical Methods, Procedure 1* or *Procedure 2*.

Acceptance criteria

Procedure 1: The ratio of the corrected absorbance [A_{325}] to the observed absorbance A_{325} is NLT 0.85.

Procedure 2: The absorption maximum is between 325 and 327 nm. The absorbance ratios are as follows: A_{300}/A_{326} is NMT 0.60; A_{350}/A_{326} is NMT 0.54; and A_{370}/A_{326} is NMT 0.14.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, preferably under an atmosphere of an inert gas, protected from light.

Change to read:

• **Labeling:** Label it to indicate the form in which the vitamin is present, and to indicate the presence of any antimicrobial agent, dispersant, antioxidant, or other added substance, and to indicate the vitamin A activity in terms of the equivalent amount of retinol, in mg/g. ▲▲ (USP 1-Aug-2019)

Add the following:

▲• **USP Reference Standards ⟨11⟩**

USP Retinyl Acetate RS

USP Retinyl Palmitate RS▲ (ERR 1-Jan-2019)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
VITAMIN A	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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